

REMARKS/ARGUMENTS

The Office Action mailed December 16, 2003 has been carefully reviewed. Reconsideration of this application, as amended and in view of the following remarks, is respectfully requested. Claims 1-9 were in the application. Claim 2 has been cancelled. The claims presented for examination are: claims 1, and 3-9.

35 USC 112 Rejection

In numbered paragraphs 2 and 3 of the Office Action mailed December 16, 2003, claims 1-9 were rejected under 35 USC 112 as having an omitted step of the pathogens to binding to the antibodies. Independent claim 1 has been amended in response to the 35 USC 112 rejection. All of the other claims presented for examination depend from amended independent claim 1.

Independent claim 1 has been amended to include the step, "allowing pathogens to bind to the antibodies." Support for the addition of this step is found in the original specification. For example, the following portion of the specification shows support for the step:

"The pathogen streaming by the electrode surfaces attach to the immobilized antibodies, as seen in Figure 4, and thus changes the impedance between the two electrodes, which is measured, as by the sensor of Figure 7, to detect the presence of a pathogen." (Page 6, lines 13-16)

"As sample fluid streams pass the immobilized antibodies 22 on electrodes 20 and 18, pathogens in the sample fluid attach to the immobilized antibodies 22 as shown by pathogen 24 in Figure 4." (Page 8, lines 3-5)

Applicants believe that amended claim 1 and the dependent claims 3-9 comply with the requirements of 35 USC 112.

35 USC 102(b) Rejection – Setter et al

In numbered paragraph 5 of the Office Action mailed December 16, 2003, claims 1, 4, and 7 were rejected under 35 USC 102(b) as allegedly being anticipated by Setter et al (U.S. Pat. 5,567,301).

Applicants have amended independent claim 1 in the application. All of the remaining claims depend from claim 1. The amended claim 1 includes the steps, “providing beads coated with antibodies that bind to pathogens” and “directing a sample fluid containing pathogens, antibodies, and beads past the spaced electrodes.” Support for the addition of these steps is found in the original specification. For example, the following portion of the specification shows support for the steps:

“To amplify the impedance change signal, one or more beads 25 coated with antibodies can be introduced to the signal area (electrodes 20-18) as shown in Figure 5. The coated bead or beads 25 stick to the pathogen 24 and further add to the change in impedance between the electrodes 20 and 18.” (Page 8, lines 10-13)

Applicant respectfully submits that the Setter et al reference does not show the steps of amended claim 1 now presented for examination. For example, the steps, “providing beads coated with antibodies that bind to pathogens” and “directing a sample fluid containing pathogens, antibodies, and beads past the spaced electrodes” are not shown by Setter et al. All of the other claims presented for examination depend from amended independent claim 1. As stated in Verdegaal Bros. v. Union Oil Co. of California, 814 F.2nd 628, 631 USPQ 1051, 1053 (Fed. Cir. 1987), “A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described in a single prior art reference.” Since steps of the claims now presented for examination are

not shown by the Setter et al reference, the rejection is unsupported by the art and should be withdrawn.

35 USC 102(b) Rejection – Clerc

In numbered paragraph 6 of the Office Action mailed December 16, 2003, claims 1, 4, and 7 were rejected under 35 USC 102(b) as allegedly being anticipated by Clerc (U.S. Pat. 6,133,046).

Applicants have amended independent claim 1 in the application, the remaining claims depend from claim 1. The amended claim 1 includes the step, “allowing the pathogens to bind to antibodies.” Support for the addition of this element is found in the original specification. For example, the following portion of the specification shows support for the element:

“To amplify the impedance change signal, one or more beads 25 coated with antibodies can be introduced to the signal area (electrodes 20-18) as shown in Figure 5. The coated bead or beads 25 stick to the pathogen 24 and further add to the change in impedance between the electrodes 20 and 18.” (Page 8, lines 10-13)

Applicant respectfully submits that the Clerc reference does not show the steps, “providing beads coated with antibodies that bind to pathogens” and “directing a sample fluid containing pathogens, antibodies, and beads past the spaced electrodes.” All of the other claims presented for examination depend from amended independent claim 1. As stated in Verdegaal Bros. v. Union Oil Co. of California, 814 F.2nd 628, 631 USPQ 1051, 1053 (Fed. Cir. 1987), “A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described in a single prior art reference.” Since steps of the claims now presented for examination are not shown by the Clerc reference, the rejection is unsupported by the art and should be withdrawn.

35 USC 102(b) Rejection – Vadgama et al

In numbered paragraph 7 of the Office Action mailed December 16, 2003, claims 1 and 3-7 were rejected under 35 USC 102(b) as allegedly being anticipated by Vadgama et al (WO 98/19153).

Applicants have amended independent claim 1 in the application, the remaining claims depend from claim 1. The amended claim 1 includes the steps, “providing beads coated with antibodies that bind to pathogens” and “directing a sample fluid containing pathogens, antibodies, and beads past the spaced electrodes.” Support for the addition of these steps is found in the original specification. For example, the following portion of the specification shows support for the steps:

“To amplify the impedance change signal, one or more beads 25 coated with antibodies can be introduced to the signal area (electrodes 20-18) as shown in Figure 5. The coated bead or beads 25 stick to the pathogen 24 and further add to the change in impedance between the electrodes 20 and 18.” (Page 8, lines 10-13)

Applicant respectfully submits that the Vadgama et al reference does not show steps of amended claim 1 now presented for examination. For example, the steps, “providing beads coated with antibodies that bind to pathogens” and “directing a sample fluid containing pathogens, antibodies, and beads past the spaced electrodes” are not shown by Vadgama et al. All of the other claims presented for examination depend from amended independent claim 1. As stated in Verdegaal Bros. v. Union Oil Co. of California, 814 F.2nd 628, 631 USPQ 1051, 1053 (Fed. Cir. 1987), “A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described in a single prior art reference.” Since steps of the claims now presented for examination are

not shown by the Vadgama et al reference, the rejection is unsupported by the art and should be withdrawn.

35 USC 102(b) Rejection – Van Gerwen et al

In numbered paragraph 8 of the Office Action mailed December 16, 2003, claims 1 and 3-7 were rejected under 35 USC 102(b) as allegedly being anticipated by Van Gerwen et al (WO 97/21094).

Applicants have amended independent claim 1 in the application, the remaining claims depend from claim 1. The amended claim 1 includes the steps, “providing beads coated with antibodies that bind to pathogens” and “directing a sample fluid containing pathogens, antibodies, and beads past the spaced electrodes.” Support for the addition of these steps is found in the original specification. For example, the following portion of the specification shows support for the steps:

“To amplify the impedance change signal, one or more beads 25 coated with antibodies can be introduced to the signal area (electrodes 20-18) as shown in Figure 5. The coated bead or beads 25 stick to the pathogen 24 and further add to the change in impedance between the electrodes 20 and 18.” (Page 8, lines 10-13)

Applicant respectfully submits that the Van Gerwen et al reference does not show steps of amended claim 1 now presented for examination. For example, the steps, “providing beads coated with antibodies that bind to pathogens” and “directing a sample fluid containing pathogens, antibodies, and beads past the spaced electrodes” are not shown by Van Gerwen et al. All of the other claims presented for examination depend from amended independent claim 1. As stated in Verdegaal Bros. v. Union Oil Co. of California, 814 F.2nd 628, 631 USPQ 1051, 1053 (Fed. Cir. 1987), “A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described in a single

prior art reference.” Since steps of the claims now presented for examination are not shown by the Van Gerwen et al reference, the rejection is unsupported by the art and should be withdrawn.

35 USC 103 Rejection - Vadgama et al or Van Gerwen et al

In numbered paragraph 12 of the Office Action mailed December 16, 2003, claim 9 was rejected under 35 USC 103(a) as allegedly being unpatentable over Vadgama et al (WO 98/19153) or Van Gerwen et al (WO 97/21094).

Applicants have amended independent claim 1 in the application, the remaining claims depend from claim 1. The amended claim 1 includes the steps, “providing beads coated with antibodies that bind to pathogens” and “directing a sample fluid containing pathogens, antibodies, and beads past the spaced electrodes.” Support for the addition of these steps is found in the original specification. For example, the following portion of the specification shows support for the steps:

“To amplify the impedance change signal, one or more beads 25 coated with antibodies can be introduced to the signal area (electrodes 20-18) as shown in Figure 5. The coated bead or beads 25 stick to the pathogen 24 and further add to the change in impedance between the electrodes 20 and 18.” (Page 8, lines 10-13)

The Vadgama et al (WO 98/19153) and Van Gerwen et al (WO 97/21094) references do not show or suggest the steps, “providing beads coated with antibodies that bind to pathogens” and “directing a sample fluid containing pathogens, antibodies, and beads past the spaced electrodes.” Applicants believe that amended claim 1 and the dependent claims now presented for examination overcome the foregoing 35 USC 103(a) rejection.

35 USC 103 Rejection - Clark et al or Kipling et al

In numbered paragraph 13 of the Office Action mailed December 16, 2003, claims 1, 3-4, 7, and 9 were rejected under 35 USC 103(a) as allegedly being unpatentable over Clark et al (U.S. Pat. 5,194,133) or Kipling et al (U.S. Pat. 5,374,521).

Applicants have amended independent claim 1 in the application, the remaining claims depend from claim 1. The amended claim 1 includes the steps, "providing beads coated with antibodies that bind to pathogens" and "directing a sample fluid containing pathogens, antibodies, and beads past the spaced electrodes." Support for the addition of these steps is found in the original specification. For example, the following portion of the specification shows support for the steps:

"To amplify the impedance change signal, one or more beads 25 coated with antibodies can be introduced to the signal area (electrodes 20-18) as shown in Figure 5. The coated bead or beads 25 stick to the pathogen 24 and further add to the change in impedance between the electrodes 20 and 18." (Page 8, lines 10-13)

The Clark et al (U.S. Pat. 5,194,133) or Kipling et al (U.S. Pat. 5,374,521) references do not show or suggest the steps, "providing beads coated with antibodies that bind to pathogens" and "directing a sample fluid containing pathogens, antibodies, and beads past the spaced electrodes." Applicants believe that amended claim 1 and the dependent claims now presented for examination overcome the foregoing 35 USC 103(a) rejection.

35 USC 103 Rejection – Clark et al, Kipling et al, and Taylor et al

In numbered paragraph 14 of the Office Action mailed December 16, 2003, claims 5 and 8 were rejected under 35 USC 103(a) as allegedly being

unpatentable over Clark et al (U.S. Pat. 5,194,133) in view of Kipling et al (U.S. Pat. 5,374,521) in view of Taylor et al (U.S. Pat. 5,001,048).

Applicants have amended independent claim 1 in the application, the remaining claims depend from claim 1. The amended claim 1 includes the steps, “providing beads coated with antibodies that bind to pathogens” and “directing a sample fluid containing pathogens, antibodies, and beads past the spaced electrodes.” Support for the addition of these steps is found in the original specification. For example, the following portion of the specification shows support for the steps:

“To amplify the impedance change signal, one or more beads 25 coated with antibodies can be introduced to the signal area (electrodes 20-18) as shown in Figure 5. The coated bead or beads 25 stick to the pathogen 24 and further add to the change in impedance between the electrodes 20 and 18.” (Page 8, lines 10-13)

The Clark et al (U.S. Pat. 5,194,133) and Kipling et al (U.S. Pat. 5,374,521) and Taylor et al (U.S. Pat. 5,001,048) references do not show or suggest the steps, “providing beads coated with antibodies that bind to pathogens” and “directing a sample fluid containing pathogens, antibodies, and beads past the spaced electrodes.” Applicants believe that amended claim 1 and the dependent claims now presented for examination overcome the foregoing 35 USC 103(a) rejection.

35 USC 103 Rejection – Paragraph 15

In numbered paragraph 15 of the Office Action mailed December 16, 2003, claim 8 was rejected under 35 USC 103(a) as allegedly being unpatentable over Van Gerwen et al (WO 97/21094), Vadgama et al (WO 98/19153), Setter et al (U.S. Pat. 5,567,301), or Clerc (U.S. Pat. 6,133,046) in view of Taylor et al (U.S. Pat. 5,001,048).

Applicants have amended independent claim 1 in the application, the remaining claims depend from claim 1. The amended claim 1 includes the steps, “providing beads coated with antibodies that bind to pathogens” and “directing a sample fluid containing pathogens, antibodies, and beads past the spaced electrodes.” Support for the addition of these steps is found in the original specification. For example, the following portion of the specification shows support for the steps:

“To amplify the impedance change signal, one or more beads 25 coated with antibodies can be introduced to the signal area (electrodes 20-18) as shown in Figure 5. The coated bead or beads 25 stick to the pathogen 24 and further add to the change in impedance between the electrodes 20 and 18.” (Page 8, lines 10-13)

The Van Gerwen et al (WO 97/21094), Vadgama et al (WO 98/19153), Setter et al (U.S. Pat. 5,567,301), Clerc (U.S. Pat. 6,133,046), and Taylor et al (U.S. Pat. 5,001,048) references do not show or suggest the steps, “providing beads coated with antibodies that bind to pathogens” and “directing a sample fluid containing pathogens, antibodies, and beads past the spaced electrodes.” Applicants believe that amended claim 1 and the dependent claims now presented for examination overcome the foregoing 35 USC 103(a) rejection.

35 USC 103 Rejection – Paragraph 16

In numbered paragraph 16 of the Office Action mailed December 16, 2003, claim 2 was rejected under 35 USC 103(a) as allegedly being unpatentable over Van Gerwen et al (WO 97/21094), Vadgama et al (WO 98/19153), Setter et al (U.S. Pat. 5,567,301), or Clerc (U.S. Pat. 6,133,046) in view of Pyle et al (U.S. Pat. 5,821,066).

Applicants have amended independent claim 1 in the application, the remaining claims depend from claim 1. The amended claim 1 includes the steps,

“providing beads coated with antibodies that bind to pathogens” and “directing a sample fluid containing pathogens, antibodies, and beads past the spaced electrodes.” Support for the addition of these steps is found in the original specification. For example, the following portion of the specification shows support for the steps:

“To amplify the impedance change signal, one or more beads 25 coated with antibodies can be introduced to the signal area (electrodes 20-18) as shown in Figure 5. The coated bead or beads 25 stick to the pathogen 24 and further add to the change in impedance between the electrodes 20 and 18.” (Page 8, lines 10-13)

The Van Gerwen et al (WO 97/21094), Vadgama et al (WO 98/19153), Setter et al (U.S. Pat. 5,567,301), Clerc (U.S. Pat. 6,133,046), and Pyle et al (U.S. Pat. 5,821,066) references do not show or suggest the steps, “providing beads coated with antibodies that bind to pathogens” and “directing a sample fluid containing pathogens, antibodies, and beads past the spaced electrodes.”

Applicants believe that amended claim 1 and the dependent claims now presented for examination overcome the foregoing 35 USC 103(a) rejection.

35 USC 103 Rejection – Paragraph 17

In numbered paragraph 17 of the Office Action mailed December 16, 2003, claim 2 was rejected under 35 USC 103(a) as allegedly being unpatentable over Clark et al (U.S. Pat. 5,194,133) or Kipling et al (U.S. Pat. 5,374,521) in view of Pyle et al (U.S. Pat. 5,821,066).

Applicants have amended independent claim 1 in the application, the remaining claims depend from claim 1. The amended claim 1 includes the steps, “providing beads coated with antibodies that bind to pathogens” and “directing a sample fluid containing pathogens, antibodies, and beads past the spaced electrodes.” Support for the addition of these steps is found in the original

specification. For example, the following portion of the specification shows support for the steps:

“To amplify the impedance change signal, one or more beads 25 coated with antibodies can be introduced to the signal area (electrodes 20-18) as shown in Figure 5. The coated bead or beads 25 stick to the pathogen 24 and further add to the change in impedance between the electrodes 20 and 18.” (Page 8, lines 10-13)

The Clark et al (U.S. Pat. 5,194,133) and Kipling et al (U.S. Pat. 5,374,521) and Pyle et al (U.S. Pat. 5,821,066) references do not show or suggest the steps, “providing beads coated with antibodies that bind to pathogens” and “directing a sample fluid containing pathogens, antibodies, and beads past the spaced electrodes.” Applicants believe that amended claim 1 and the dependent claims now presented for examination overcome the foregoing 35 USC 103(a) rejection.

35 USC 103 Rejection – Paragraph 18

In numbered paragraph 18 of the Office Action mailed December 16, 2003, claims 1-9 were rejected under 35 USC 103(a) as allegedly being unpatentable over Miles (U.S. 2002/0070114) in view of Kipling et al (U.S. Pat. 5,374,521).

The Miles et al. (U.S. 2002/0070114) Reference and the subject patent application are both owned by the Regents of the University of California as evidenced by assignments recorded in the United States Patent and Trademark Office. The Miles et al. (U.S. 2002/0070114) Reference shows on its face that it is assigned to and owned by the Regents of the University of California. The subject application is also owned by the Regents of the University of California. On December 14, 2000 an assignment was filed in the parent application showing that the parent application; and therefore the subject divisional application, is owned by the Regents of the University of California.

35 USC 103 Rejection – Paragraph 19

In numbered paragraph 19 of the Office Action mailed December 16, 2003, claims 1-9 were rejected under 35 USC 103(a) as allegedly being unpatentable over Krulevitch et al (U.S. Pat. 6,437,551) in view of Kipling et al (U.S. Pat. 5,374,521).

The Krulevitch et al (U.S. Pat. 6,437,551) Reference and the subject patent application are both owned by the Regents of the University of California as evidenced by assignments recorded in the United States Patent and Trademark Office. The Krulevitch et al (U.S. Pat. 6,437,551) Reference shows on its face that it is assigned to and owned by the Regents of the University of California. The subject application is also owned by the Regents of the University of California. On December 14, 2000 an assignment was filed in the parent application showing that the parent application; and therefore the subject divisional application, is owned by the Regents of the University of California.

Response to Double Patenting Rejection - Paragraph 20

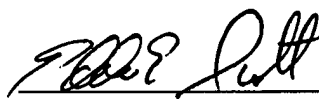
In numbered paragraph 20 of the Office Action mailed December 16, 2003 claims 1-9 were provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being allegedly unpatentable over claims 12-15 of copending U.S. Patent Application No. 09/737,927 filed on December 14, 2000 and published as U.S. Patent Application No. 2002/0070114 on June 20, 2002 in view of the Kipling et al. (U.S. Pat. 5,374,521) Reference.

A terminal disclaimer in compliance with 37 CFR §321(c) in the form of a "DECLARATION UNDER 37 CFR §1.130(b), disclaiming the terminal portion of any patent granted on the subject application beyond the expiration date of any patent issued upon et al. (U.S. 2002/0070114)" is enclosed.

SUMMARY

The undersigned respectfully submits that, in view of the foregoing amendments and the foregoing remarks, the rejections of the claims raised in the Office Action dated December 16, 2003 have been fully addressed and overcome, and the present application is believed to be in condition for allowance. It is respectfully requested that this application be reconsidered, that the claims be allowed, and that this case be passed to issue. If it is believed that a telephone conversation would expedite the prosecution of the present application, or clarify matters with regard to its allowance, the Examiner is invited to call the undersigned attorney at (925) 424-6897.

Respectfully submitted,



Eddie E. Scott
Attorney for Applicant
Registration No. 25,220
Tel. No. (925) 424-6897

Livermore, California

Dated: February 19, 2004